Date:

\* ***Please note*** - If the Researcher is a **student** or **JABSOM resident**, per UH policy, the Faculty Advisor serves as the Principal Investigator and the student or JABSOM resident serves as the Co - Investigator.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Principal Investigator (P.I.) /* ***if student****, Co - Investigator Name:* | | |  | | | | |  |
| Email address: |  | | | Phone number: | | |  |  |
| Department: |  | | | | Campus: |  | |  |
|  | | | | | | | | |
| Student’s Faculty Advisor / Principal Investigator Name: | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | |  |
| Advisor email address: |  | | | | Advisor phone number: |  | |  |
| |  |  |  |  | | --- | --- | --- | --- | | (If applicable) Administrative contact name: |  | Administrative email: |  | | | | | | | | | |
| **Title of Research Project:**  **CHS#****\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | |

The funding agencies of the study:       Not applicable to my study

1. **Approval Period**

Date of last Review:       Date Current IRB Authorization Expires:

|  |  |  |
| --- | --- | --- |
| Reason for Status Report: | | **Date of Status Report Request**: |
| **Report Period** (i.e. quarterly, annual): |
|  |  | **Status Report #** |
| **Update**: | | |

2. **Study Enrollment**: Please answer a. through g. below for all sites operating under UH IRB approval:

1. Enrollment status:   open  closed  Date Closed:        not applicable
2. IRB-approved enrollment target:
3. Number of participants screened: during this review period =      ; total screened to date =
4. Number of participants enrolled: during this review period =      ; total enrolled to date =
5. If there was no enrollment since the last approval, please explain why:
6. Number of participants in follow - up status:       Not applicable to my study
7. What is the remaining length of time in your research project?

**For Cooperative IRB Studies Only**

Indicate institutions participating with the UH Cooperative IRB for this research project:

Hawaii Pacific Health  Queen’s Health Systems  Castle Medical Center

**Total number of deaths to date:**

**Total number currently in active treatment:**

**Hawaii Pacific Health**

Number of participants screened: during this review period =      ; total screened to date =

Number of participants enrolled: during this review period =      ; total enrolled to date =

Number of participants in follow - up status:

**Queen’s Health Systems**

Number of participants screened: during this review period =      ; total screened to date =

Number of participants enrolled: during this review period =      ; total enrolled to date =

Number of participants in follow - up status:

**Castle Medical Center**

Number of participants screened: during this review period =      ; total screened to date =

Number of participants enrolled: during this review period =      ; total enrolled to date =

Number of participants in follow - up status:

**Other Institutions in Hawai'i**

Number of participants screened: during this review period =      ; total screened to date =

Number of participants enrolled: during this review period =      ; total enrolled to date =

Number of participants in follow - up status:

**Institutions Outside of Hawai'i**

Number of participants screened: during this review period =      ; total screened to date =

Number of participants enrolled: during this review period =      ; total enrolled to date =

Number of participants in follow - up status:

3. Was a consent form approved by the IRB for this study?  Yes  No  NA

1. Describe the study purpose and objectives.

1. Append to this application:
2. The current version of any IRB-approved consent form(s) and assent form(s).
3. Any audit, inspection, multi-center trial, and DSMB (Data and Safety Monitoring Board) reports received during the period.
4. Proposed study modifications (please submit using the Modification Request Form).
5. Documentation of training requirements completed during the review period.
6. Documents that provide information requested above (e.g., summary of protocol violations, unanticipated problems, etc.)
7. Most recent disclosure of financial conflicts of interest and management plan of the conflict if, in this past year, your supervisor has determined that you have a conflict of interest.

\*Note: you must disclose the conflict in the consent document.

Certification*: I certify that the information provided in this continuing review application is accurate and complete to the best of my knowledge, and I agree to conduct this study in compliance with applicable federal regulations, Human Studies Program policies, and IRB determinations. Furthermore, I will submit a modification form documenting any future changes to this study.*

Signed: Date:

Principal Investigator/ Advising Professor

Signed: Date:

Co-Investigator (if researcher is a student)

**Instructions and Glossary of Key Terms**

**Instructions:** Provide succinct answers to all questions on the application form. If you have questions, call the Human Studies Program office at 956-5007. Please submit your application for continuing review, with appendices, to the Human Studies Program at least **one month** before the study expiration date.

Please email your continuing review application to [uhirb@hawaii.edu](mailto:uhirb@hawaii.edu). In the subject line, write “Continuing Review Application” and the file number. Also, provide 2 collated hard copies delivered to the University of Hawaii Human Studies Program, 1960 East-West Road, Biomedical Bldg B-104, Honolulu, HI 96822. All applications must include the signature of the P.I.

**Glossary of Key Terms**

**Adverse Event**: An Adverse Event (AE) means any unfavorable medical occurrence in a human participant, including any abnormal sign such as abnormal physical exam or laboratory findings, symptom, or disease, temporally associated with the subject's participation in the research, regardless whether considered related to the subject's participation in the research. It encompasses both a physical and a psychological harm.

**Minor Protocol Violation:** A protocol violation that does not impact the safety or welfare of study participants, compromise the integrity of study data, or affect participants’ willingness to participate in the study.

**Major Protocol Violation:** A protocol violation that may impact the safety or welfare of study participants, compromises the integrity of study data, or affects participants’ willingness to participate in the study.

**Protocol Violation:** Any deviation, change or departure from the IRB-approved protocol that does not have prior approval by the IRB unless the change is necessary to remove an apparent immediate hazard to one or more study participants. For additional information on protocol violations, see Standard Operating Policy and Procedure (SOPP) 104, Reporting Protocol Violations to the IRB, available on the website at <https://manoa.hawaii.edu/researchcompliance/policies-guidance>.

**Unanticipated Problem (UP):** Any incident, experience, or outcome that meets all of the following criteria:

* Unexpected (in terms of nature, severity, or frequency) given:
  + (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and consent form; and
  + (b) the characteristics of the participant population being studied.
* Related or possibly related to participation in the research protocol where “possibly related”means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures or interventions involved in the research; and
* Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Examples of UPs include occurrences of breaches of confidentiality, accidental destruction of study records, unaccounted for study drug, or one or more serious adverse events. For additional information on reporting UPs to the IRB, see Standard Operating Policy and Procedure (SOPP) 101, Reporting and Reviewing Unanticipated Problems, available on the website at <https://manoa.hawaii.edu/researchcompliance/policies-guidance>.

**Vulnerable Populations:** Children/minors, prisoners, pregnant women, neonates, substance abusers, individuals with a serious impairment or illness, or anyone else who may be vulnerable to coercion, undue influence, or unable to consent to participate in research.